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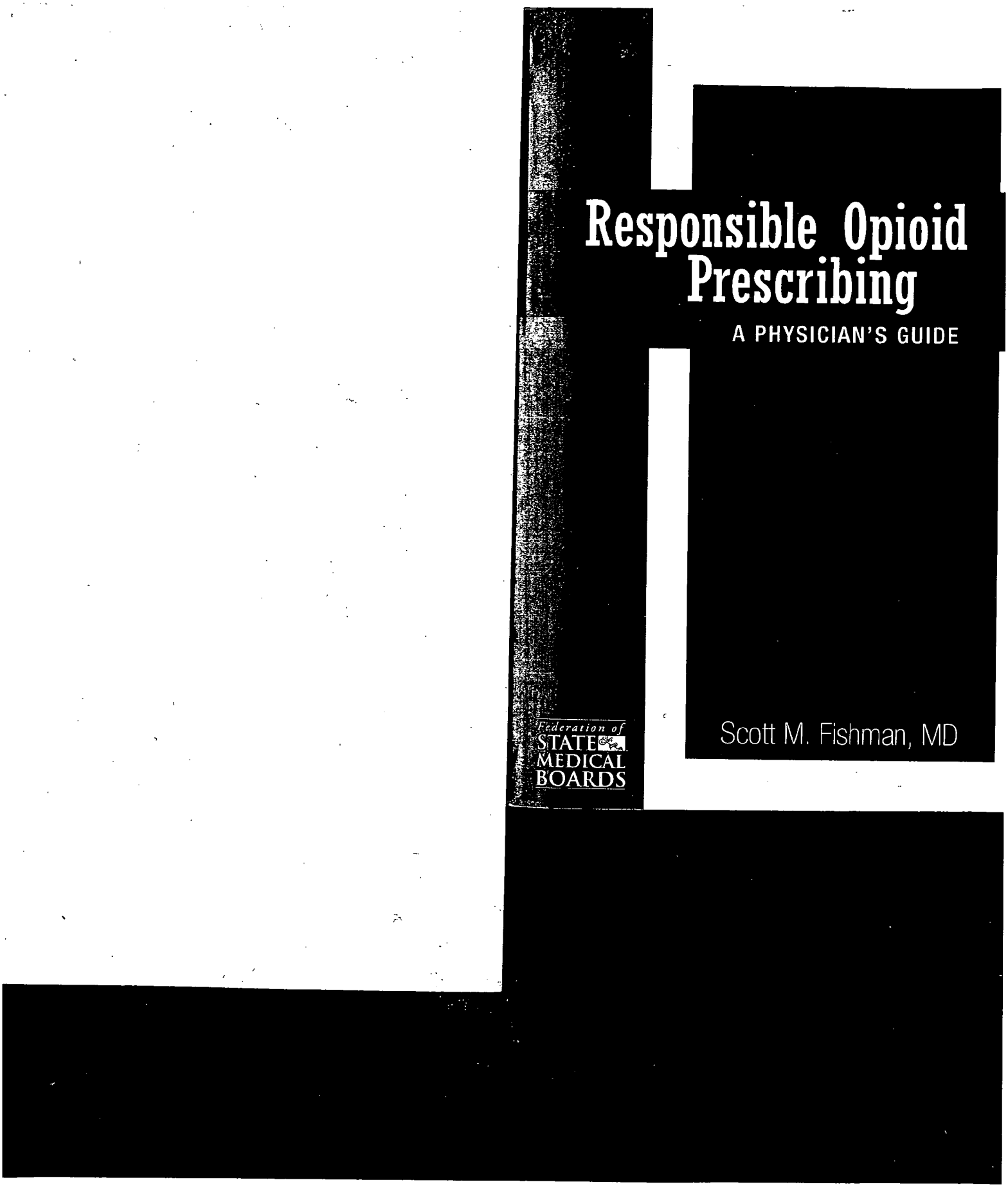
Responsible Opioid Prescribing
A PHYSICIAN'S GUIDE
Scott M. Fishman, MD
Federation of STATE MEDICAL BOARDS

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WATERFORD LIFE SCIENCES
Washington, DC

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Foreword

By James N. Thompson, MD
President and CEO, Federation of State Medical Boards

Hippocrates' seemingly straightforward directive to "First, do no harm" is anything but simple in today's medical practice. Nowhere is its complexity more evident, and vexing, than in pain management with controlled substances—particularly with opioids.

Patients in pain who rely on opioids for analgesia and improved function deserve access to safe and effective medication; to deprive them of optimal pain-relief certainly does them harm. Yet these same life-restoring medications carry the potential to do grave harm to patients who may be at risk for addiction and abuse. Significant quantities of prescription opioids are diverted into an illegal black market that puts millions of non-medical "recreational" users at risk of addiction and death—many of them young adults and teenagers. Very few physicians are complicit in this criminal diversion, and there are no proven methods for preventing patients from deceptively acquiring prescriptions—pain, after all, is a subjective symptom for which there are no foolproof diagnostic tests. But the fact that some patients will deceive a physician in order to obtain prescription opioids for non-medical use requires us to be vigilant when prescribing these potent and potentially abusable medications.

Physicians cannot single-handedly eliminate the diversion and abuse of prescription opioids. *But we have a solemn responsibility—to our patients and to society—to be vigilant in reducing these risks.* Too few physicians have educated themselves about the simple steps they can take to become more responsible opioid prescribers.

Sadly, many physicians have sought to reduce the risks of opioid prescribing—including the tangible risk to a physician's own licensure if he or she prescribes outside the standards of medical care—by simply not treating patients in pain, or by not treating them with controlled substances. But as pain treatment becomes increasingly intertwined in the larger medical mission of patient care, it's increasingly important for physicians to become sophisticated about the risks and benefits of opioid therapy—the risks of diversion, abuse, and addiction as well as the benefits in managing acute and chronic pain.

Physicians who prescribe opioids are obliged to comply with both state regulations and the federal Controlled Substances Act. In 2005, there were approximately 720,290 Medical Doctors (MDs) and Doctors of Osteopathic Medicine (DOs) registered with the Drug Enforcement Administration (DEA). All physicians should be familiar with the clinical practices that will help them comply with state and federal statutes.

The Federation of State Medical Boards (FSMB) has commissioned this book and is distributing it to physicians to offer clear and concise guidance in managing the risks of pain management with opioids. Incorporating these strategies into your practice will help you fulfill your dual responsibilities to your patients and to your state and federal licensing authorities.

This book grows out an initiative launched a decade ago by the FSMB to create its *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain.* These consensus guidelines were formulated with input from the major stakeholders on all sides of the issue, including leading pain and addiction specialists, medical societies, state medical boards, and federal law enforcement agencies including the DEA. These guidelines, which were subsequently updated to a *Model Policy* in 2004, have been praised as "well balanced" by such groups as the Pain and Policy Study Group of the University of Wisconsin.* Twenty-eight state medical boards have adopted the Guidelines or *Model Policy* verbatim as their state guidelines, and ten other states have adopted guidelines with similar language.

The FSMB's *Model Policy* distills safe opioid prescribing into seven concise principles:

1. Evaluation of the Patient
2. Treatment Plan
3. Informed Consent and Agreement for Treatment
4. Periodic Review
5. Consultation
6. Medical Records
7. Compliance With Controlled Substances Laws and Regulations

Although the *Model Policy* represents the most concise consensus guidelines for safe opioid prescribing, until now this document has not been translated into practical terms for clinical practice. Consequently, few physicians are

* *For more information see www.medsch.wisc.edu/painpolicy*

familiar with these guidelines, and even fewer utilize them in their practice.

This book answers that unmet physician need by explaining how to incorporate the *Model Policy* into your real-life practice. Its author, Scott M. Fishman, MD, is Past President of the American Academy of Pain Medicine and a true thought leader in academic medicine, clinical practice, and public health policy. Dr. Fishman has worked closely with the FSMB on establishing the current *Model Policy* and has been a champion for safe and effective prescribing for pain management.

After reading this book, you'll understand simple steps you can take to comply with state and federal regulations regarding controlled substance prescribing for pain. FSMB's website (www.fsmb.org/pain) will keep this book updated and offers valuable links to state-by-state regulations and other useful websites to help facilitate pharmacovigilant opioid prescribing in your practice.

The term "pharmacovigilance" is one Hippocrates would surely have grasped. It derives from the Greek *pharmakon*, "drug;" and the Latin *vigilare*, "to keep awake and alert, to keep watch." In modern parlance, it refers to watchfully monitoring and managing the risks of adverse events and side effects of any medication, regardless of the class of drug. Becoming a pharmacovigilant opioid prescriber requires that we understand the risks specific to opioid analgesics and take simple steps to manage them.

Armed with the information in this essential handbook, we can each reaffirm our commitment to "First, do no harm."

Introduction: Pharmacovigilance and Good Medicine

Over the past decade, two important public health trends have become entwined like the twin serpents in the caduceus: (1) increasing clinical attention across all medical specialties to the undertreatment of pain, and (2) shifting patterns of drug abuse from illicit to prescription drugs—most notably a dramatic rise in diversion and non-medical use of opioid pain medications within the United States. The collision between the War on Pain and the War on Drugs has created a "perfect storm" of controversy. And, for better or worse, physicians are being enlisted to fight on both fronts: combating pain while simultaneously reducing the risk of diversion and abuse of, as well as addiction to, pain medications.

Many of us bristle at adding "pharmacovigilance" and "risk management" to our already lengthy task list. But the combination of potential therapeutic benefit and high risk associated with opioid* analgesics leave us no alternative but to become more sophisticated risk managers. Millions

** The term opioid refers to natural and semi-synthetic derivatives of the opium poppy, as well as similar synthetic compounds that have analgesic or pain relieving properties because of their effects in the central nervous system. These include codeine, morphine, hydromorphone, hydrocodone, oxycodone, methadone, and fentanyl among others. Opioids are often inappropriately referred to as narcotics, a legal term that is no longer used in medicine because it suggests that opioids relieve pain by inducing sedation; while sedation can be a side effect of opioids, it is not the mechanism that produces pain relief.*

of legitimate patients rely on these medications for pain relief and functional improvement, so we must include them in our repertoire of potential medication therapies. However, we cannot ignore the potential risks associated with the use of controlled substances, including addiction.

Managing risk is what we physicians do every day with every patient, whether we're considering procedures, medications, or non-medication interventions. Every treatment plan carries potential risks, as does the decision not to treat. Managing risks associated with opioids is fundamentally the same as pharmacovigilance concerning adverse reactions to any class of drugs: essentially following sound principles of medical practice and prescribing and achieving transparency in treatment decisions. The difference with opioids is that these drugs are increasingly diverted or otherwise abused.

Scope of the Problem

A statistical snapshot of prescription drug abuse and diversion in the United States reveals the scope of this alarming public health crisis:

- In 2005 (the latest year for which data are available), more than 10 million Americans were abusing prescription drugs—which is more than the combined number of people abusing cocaine, heroin, hallucinogens, and inhalants.
- The Centers for Disease Control and Prevention report that prescription opioids are now associated with more drug overdose deaths than cocaine and heroin combined: between 1999 and 2002, there was a 91.2 percent increase in the reporting of opioid analgesics on death certificates.[1]

- Continuing a decade's long trend, in 2005 more new drug users began abusing pain relievers (2.2 million) than marijuana (2.1 million) or cocaine (872,000). By comparison, in 1990 only an estimated 628,000 people initiated illicit use of pain killers.[2]
- Data from a set of selected states show that almost 13,000 incidents of prescription controlled substances were diverted by theft from 2000 to 2003. In 2003 alone, 2 million dosages of six opioid analgesics were reported stolen from the supply chain, mainly from retail pharmacies.[3]

Behind these figures lie millions of individual stories of personal tragedy: untimely death, fractured families, shattered dreams, and wasted lives. Certainly the same spectrum of ills can be found in the wake of any abused drug, but the magnitude of the current problem makes it imperative that physicians become vigilant risk managers who demonstrate transparency in the decisions behind the care they deliver.

Much remains to be learned about the nature of prescription drug abuse in the United States. For example, the exact contribution of prescribers to prescription drug diversion and abuse is not presently known. Because the rise of prescription drug abuse has occurred alongside increased use of opioids in legitimate pain relief, it is tempting to assume cause and effect. However, preliminary evidence does not support this conclusion and more information about how prescription drugs are diverted is crucially needed. If we are to have responsible and effective responses to prescription drug abuse, the problem must be

considered in its full context. To avoid penalizing those with legitimate needs, solutions must factor in the full complexity of drug abuse, addiction and all of the related social and medical disorders. In particular, we must be careful with implications that prescription drug abuse is mostly related to prescribers and their patients, and be careful with implying that limiting medically appropriate use may have significant effects on reversing this disturbing trend.

A Countervailing Need

Concurrent with the epidemic of prescription drug abuse, patients and patient advocates have been pushing to address the equally legitimate cause of undertreated pain. Although these efforts began in the relatively circumscribed spheres of end-of-life care and cancer-related pain, medicine has appropriately widened its perspective to include all debilitating pain that has lost its purpose as an adaptive alarm signal, regardless of the source.

Significant effort has been made to reduce the incidence of untreated or undertreated pain in children, older patients, and in all other vulnerable patient populations. And at least at the level of clinical guidelines, policy statements, and organizational goals, the following general principles are widely accepted:

- Pain management is integral to good medical practice for all patients;
- Opioid therapy to relieve pain and improve function is a legitimate medical practice for acute and chronic pain of both cancer and non-cancer origins;

- Patients should not be denied opioid medications except in light of clear evidence that such medications are harmful to the patient;
- The use of opioids for other than legitimate medical purposes poses a threat to the individual and society; and
- Physicians have a responsibility to minimize the potential for the abuse and diversion of controlled substances.

If opioids had no medically redeeming value, the issue of their abuse would be tragic but physicians would have no role to play in minimizing abuse by changing their behaviors or monitoring their actions. The current need for guidance on opioid prescribing arises from the fact that, as addictive and life-destroying as opioids can be for some, they are life-enhancing and non-addictive for others.

Four key factors contribute to the ongoing problem of under-treated pain:

1. Lack of knowledge of medical standards, current research, and clinical guidelines for appropriate pain treatment;
2. The perception that prescribing adequate amounts of opioids will result in unnecessary scrutiny by regulatory authorities;
3. Misunderstanding of addiction and dependence; and
4. Lack of understanding of regulatory policies and processes.

To these factors might be added a fifth: the lack of clearly written government regulations and professional guidelines for prescribing, or assistance with how to easily and efficiently incorporate these approaches into the hectic daily practice of physicians.

Filling an Unmet Need

This book is intended to help the responsible clinician understand and implement practices that support rational and transparent opioid prescribing. The following chapters examine each of the seven steps in the FSMB's *Model Policy*:

1. Patient Evaluation
2. Treatment Plan
3. Informed Consent and Agreement for Treatment
4. Periodic Review
5. Referral and Patient Management
6. Documentation
7. Compliance With Controlled Substance Laws and Regulations

Each of these steps, which are only briefly described in the *Model Policy*, are here given an expanded discussion from the perspective of real-world clinical practice. Most physicians already perform many of the key steps recommended in the *Model Policy*. This book focuses on explanations and techniques that specifically address the issues that arise when prescribing opioids. Sometimes this simply means adhering to existing standards of care. At other times—such as in the creation of function-based treatment plans—a significant paradigm shift in perspective will be presented that translates into novel models for creating, monitoring, and modifying treatment goals for your patients in pain.

Prescription drug abuse and undertreated pain are both serious public health crises, but the solution to one need not undermine the other. The least we clinicians can do is make sure that the casualties of this clash are not suffering

patients who legitimately deserve relief. Informed clinicians can take simple steps to ensure that opioids are prescribed safely and transparently—and in the process, those prescribers can justify their decisions should they encounter the scrutiny of regulators.

Regulators and law enforcement agencies, such as the Drug Enforcement Administration, have urged prescribers to be vigilant when prescribing abusable drugs, particularly for patients with known or suspected risk of abuse. Clearly, effective solutions must address the current state of inadequate education that most clinicians receive on safe and effective prescribing of controlled substances. This book is intended as a much-needed step in that direction. Unfortunately, simply knowing the tenets of the FSMB *Model Policy* will not be of value without a basic knowledge of pain, substance abuse, and their treatment. Although this book will not serve this role, other resources are available, many of which are recommended in Appendix A. Moreover, this book will not substitute for maintaining the desire to relieve suffering or the recognition that an important part of mitigating pain is simply being present with your patients and showing them that you care. Although the elements of care described here are critically important for maintaining appropriate delivery of controlled substances, unless you also incorporate the personal part of care, your patients will continue to feel alone and uncared for—and may even resist treatment.

As a physician who specializes in Pain Medicine, I'm optimistic about the future of pain treatment. The confusions and frustrations that currently characterize pain management may simply be the growing pains of a wiser, saner,

and more uniformly effective patient care approach. Appropriate concerns about the potentially harmful or addictive aspects of opioid medications can be balanced with the equally valid needs of optimal pain relief with adequate risk management. Medicine is all about managing risk while improving health and easing suffering; the safe and effective use of opioids is no different. Opioids are ancient drugs that have been both glorified and demonized in past centuries. It is time we found ways to harness their very real gifts while curbing their very real dangers.

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Chapter 1: Effective Patient Evaluation

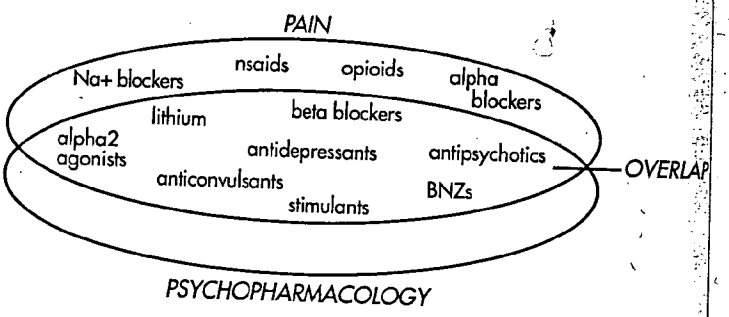
"A medical history and physical examination must be obtained, evaluated, and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. The medical record also should document the presence of one or more recognized medical indications for the use of a controlled substance."
—*FSMB Model Policy*

At the core of the requirement to evaluate patients thoroughly is a paradox: although a physician can take a history, do a physical examination, list past treatments, probe for a history of substance abuse, and note coexisting diseases, he or she cannot measure or even confirm the pain that a patient is experiencing. Despite modern diagnostic and evaluative tools, such as MRI, ultrasonography, and electromyography, pain remains an untestable hypothesis. Perhaps one reason that physicians are reluctant to aggressively treat pain has to do with the often frustrating fact that we can't prove that someone is or is not in pain, just as we can't prove the presence or absence of pain relief. However real pain is to a patient, it remains subjective to

the physician. As Elaine Scarry notes in her book *The Body in Pain*: "To hear about pain is to have doubt; to experience pain is to have certainty." In the end, physicians must accept the maxim "Pain is what a patient says it is." Anyone complaining of pain is suffering from something; the physician's job is to try to figure out the cause of the suffering and to formulate a plan for reducing it.

Today it is widely recognized that pain is never simply "physical" or "psychological." The mind is *always* involved in a patient's experience of pain, and it can magnify or diminish pain perception. The almost complete overlap between the medication groups used by both psychiatrists and pain specialists attests to the inextricable links between mind and body that make meaningless the cliché phrase "the pain is all in your head." (See the graphic below.)

The Overlap of Major Drug Groups Used in Pain Medicine and Psychiatry



Pain measurement scales, such as the familiar 0 to 10 numerical pain scale or the "faces" pain rating scale, can provide some degree of guidance about a patient's experience of pain intensity, but all are open to wide variations among subjects experiencing similar problems, and within a subject at different times. Multidimensional instruments, such as the McGill Pain Questionnaire or the Brief Pain Inventory, provide a broader picture of a patient's experience, but are usually more cumbersome to administer in a busy clinic setting and, in the end, suffer the same limitations as all other attempts to measure pain.

The best way to begin assessing a patient's pain is to ask about it and listen. This may sound trivial, but, in the hurly-burly of daily clinical life, it is essential. All too often physicians become overly focused on quantifying, categorizing, and deciding how best to treat pain as a single symptom. In the process, they may not ask pertinent questions that relate to their patients' global experience of suffering, and they ultimately distance themselves from their patients. In focusing narrowly on a disease or symptom, physicians can lose the "big picture" of the whole person and thus miss important diagnostic clues that could lead to more effective interventions.

Three relatively simple steps can vastly improve taking a history from a patient in pain:

- Take control of time;
- Focus on the patient, not the pain; and
- Use reflective listening skills.

These steps can reconnect the clinician with the patient, improve the efficacy of analgesic treatments, and increase personal satisfaction.

Step 1: Take Control of Time

In some ways, this suggestion may be largely outside our control. Physicians are increasingly pressured to see more and more patients. The average patient in pain, particularly those in chronic pain, typically has a complex presentation and histories. Clinicians must be relentlessly thorough, looking under every "rock" for clues. And being a clinical professional means we withhold judgment until we have ample evidence. This is an unavoidably time-consuming process. Thus, a patient in pain is almost automatically a "difficult case."

Unfortunately, these challenges can lead clinicians in exactly the wrong direction. Instead of allotting increased time and patience to the diagnostic task, physicians confronted with "difficult" patients may *speed up* and, either consciously or unconsciously, rush to judgment in an effort to minimize time spent with an emotionally sensitive, demanding, or frustrated patient. Full adherence to the Evaluation component of the FSMB *Model Policy*, in other words, requires a commitment to spending enough time and attention to what the patient is saying both verbally and through behaviors.

Step 2: Focus on the Patient, Not the Pain

In taking a history about pain, physicians should ask questions not only about the pain itself (its location, intensity, duration, etc.), but also about the pain's collateral damage to the patient's life. To use a musical metaphor, you need to listen not just to the lyrics (the self-evident parts of what the patient says), but to the music as well (the less obvious verbal and nonverbal messages about their feelings, fears,

expectations, goals, etc.). Clinicians need to be alert to subtle warning signs of trouble and take the time to ask follow-up questions.

Pain is usually interwoven with unpleasant experiences, such as fatigue, nausea, depression, and anxiety, among others. These are absolutely vital connections for a diagnostician—if you miss them, you'll miss understanding the true dimensions of a patient's pain and possibly some of the most useful avenues for alleviating his or her suffering. For example, depression can dramatically alter pain perception—almost always for the worse. Patients may not offer unprompted information about their depression out of fear that the physician will think their pain is "all in their head." If you don't ask direct questions related to mood, or pick up on the subtle signs from the patient's answers that suggest psychosocial deterioration, you may not recognize this significant factor in the experience of pain. Similarly, many other aspects of a person's life can affect his or her pain, such as the use or abuse of licit or illicit drugs, high stress levels at work or home, or physical deconditioning because of a lack of activity.

Step 3: Use Reflective Listening Skills

Patients in chronic pain are frequently more emotional than they might be otherwise. Pain undermines our ability to cope with the ups and downs of normal life. Pain can make any of us defensive, short-tempered, or even hostile. Not only are these patients experiencing pain but, by the time they see you, they may have undergone previous treatments that either were ineffective or exacerbated their symptoms. In some cases, the tension may be

palpable and, in others, it may simply be suppressed. It must be emphasized that above all, the patient in pain wants and needs to be believed and validated. In a sense, then, treatment actually begins during the process of assessment.

An effective strategy for collecting a comprehensive history and building a successful patient-physician relationship is *reflective listening*. This means listening carefully and non-judgmentally to what your patient is saying, then reflecting it back in a slightly modified or reframed manner. Aside from allowing the clinician to confirm the accuracy of their beliefs, this gives the patients both the indication that they are being heard and a chance to correct mistaken beliefs or perceptions that could affect their care.

Using a reflective listening strategy may be easier said than done. If a patient says something at odds with the evidence, or uses threatening or hostile language, one's natural reaction is to immediately defend oneself, rebut the charges, or deny the underlying assumptions. This can quickly create confrontation or a power struggle that can be difficult to overcome. It is much more effective to take a moment before responding, and then to consciously try to simply restate what the patient just said. For example, a patient may angrily say "Doctor, those pills you gave me don't work—I told you before that I need something stronger." Even in cases where you suspect the patient may be angling for stronger and possibly riskier medications for spurious reasons, a directly confrontational approach would probably be ineffective. A better response might be something like "You seem to be irritated with me because you don't think the medications I

prescribed are working for you." Reflective listening responses such as this provide several advantages:

- They are less likely to evoke or exacerbate patient defensiveness;
- They encourage the patient to keep talking and reveal more about his or her true motives;
- They communicate respect, caring, and compassion, and encourage a therapeutic alliance; and
- They open an opportunity for the patient to correct misunderstandings or clarify exactly what he or she means.

Although reflective listening can be particularly helpful when a patient is emotional, it is a useful approach for following up on or probing answers to questions that you ask during any patient encounter.

Elements of a Comprehensive History

Comprehensive evaluation of a patient in pain usually requires moving beyond the typical list of questions asked during a general history. In most cases where pain is the chief complaint, it is certainly appropriate to begin a conversation by asking about the pain, but then it is usually advantageous to move on to the broader context and impact of that pain. Here are some points that may be useful to cover in an initial evaluation:

- Location of pain
- Character of pain (i.e., shooting or stinging, continuous or intermittent, worse at night or in the morning)
- Lowest and highest pain on 0 to 10 scale in a typical day
- Usual pain on 0 to 10 scale on a typical day (anchored by verbal descriptors)
- How and when pain started

- Exacerbating and relieving factors (i.e., stress, alcohol, other medical concerns)
- Effect of pain on sleep
- Effect of pain on mood
- Effect of pain on functioning at work
- Effect of pain on quality of personal life, such as relationships, sex, or recreation
- Is the patient involved in a legal or protracted insurance process connected to his or her chronic pain, such as a motor vehicle accident or disability case?
- What does the patient expect from medications or other treatments in terms of analgesia or recovered function?

In the course of your conversations with patients, be alert to signs that they are minimizing their pain. Although it may seem counterintuitive, some patients fail to convey the true nature and severity of their pain, which can, albeit unintentionally, undermine the effectiveness of their treatment. They may not want to disappoint their physicians or offer a distraction from treating their primary disease; they may think they should just "suck it up" and endure their pain; they may think pain is inevitable with their illness; or they may want to avoid acknowledging that their disease is progressing. Some may worry that if they mention their pain, their doctor will see them as complainers or even as drug-seekers or addicts. Many people also under-report pain because they fear that pain medications will dull their cognitive abilities, lead to addiction, or result in unmanageable side effects. And last, some patients may believe that there is value in suffering, it is their due, or that in some way they deserve to be in pain to expiate some form of "wrong-doing" or "sinfulness."

If you suspect a patient is minimizing his or her pain, reflective listening can help the patient see what you see and allow you to probe for the reasons underlying the minimizing. At some point, you might scratch your head and say "I wonder if you are the silent sufferer type?" Very few are offended by being described as "stoic," which is usually considered something of a compliment to many patients. Being seen as someone who is doing his or her part to bear the suffering is usually consoling. Regardless of the reasons for minimizing, this approach can help you take a history by allowing patients to feel that they will not be judged negatively and can speak freely and candidly about their pain.

Screening Patients for the Possibility of Addiction or Drug Abuse

All patients complaining of pain are suffering from something and deserve a physician's empathy and compassion. But a small minority of people seeking treatment may not be reliable or trustworthy. The problem for the clinician at the front line of medicine is not that such patients are bad people who are committing sins; it is that the help that such patients are asking for will not remedy their problem and may be harmful to themselves and others. This approach evokes the professional responsibility to first do no harm. It is based solely on risk management that requires you to maintain constant vigilance without impulsively rushing to judgment. This is not unusual for physicians. For instance, there is an old adage that if you don't suspect a pulmonary embolism, you'll never catch one. The same level of suspicion (without judgment)

applies to the assessment of the patient in pain. If you do not suspect the pain may be caused by a nerve injury, you may never catch neuropathic pain. If you don't suspect the possibility that someone who asks for an opioid by its brand name might have a problem with drug abuse, you may miss a valuable opportunity to help the patient.

On the other hand, allowing suspicions to foster judgmental conclusions may be equally harmful to the patient and society. A physician must, therefore, maintain a discreet but keen vigilance for potential harm from any treatment. In the case of treatments that include controlled substances, this must include the potential for deception and abuse.

Although it may sound contradictory to exhort physicians to be empathic and supportive while simultaneously probing aggressively in search of the truth (including information that the patient may not want to reveal), this is not such a difficult balance to achieve in daily practice. You can maintain a tolerant, nonjudgmental, and concerned posture yet remain persistent in your quest for the valid information required for prudent decision making.

Whenever a clinician considers treating pain with a controlled substance, such as an opioid, risk of abuse or diversion is always a possibility, no matter how remote, and must be assessed. Exactly who to suspect and when to be proactive in investigating risk factors is an area of great debate. To date, no convincing data exist to support the strategy of focusing on any one specific population or setting—which means that physicians must be vigilant with all their patients. The term "universal precautions" has been applied to this approach and, in pain care, assumes

that any patient in pain could have a drug abuse problem—just as any patient requiring a blood draw for a simple lab test could have HIV. Gourlay and Heit (2006) argue that "since there is no one behavior that is [diagnostic] of a substance use disorder, and since the prevalence of addiction in the general population is not insignificant, it is prudent to thoroughly inquire into substance use in all patients, not only those who are being treated with the opioid class of drugs. Failure to do so may leave a potentially treatable condition, such as addiction, undiagnosed and untreated."[1]

Treating everyone with the same screens, diagnostic tests, and administrative procedures can be viewed from one angle as an attempt to remove bias and essentially level the playing field so everyone is treated equally and screened thoroughly. It also could be perceived as undermining the patient-physician relationship. Despite defensible efforts to be as consistent as possible to all, as well as to cast the broadest possible surveillance, some patients or clinicians may see the universal precautions approach as a sign of distrust or evidence that the patient is being presumed guilty until proven innocent. Dealing with this may require clear education for patients as to why such procedures and practices are necessary and in their best interest.

For the actual assessment of a patient's risk of having a substance abuse problem, several tools have been developed but, to date, no single tool has been widely endorsed or thoroughly validated. CAGE is a classic rapid screen developed for alcohol abuse that can easily be modified for any abusable drug. This brief questionnaire (which can be

incorporated into a self-administered written assessment form) asks whether a patient has ever:

C: Wanted or needed to Cut down on drinking or drug use?

A: Been Annoyed or Angered by others complaining about the patient's drinking or drug use?

G: Felt Guilty about the consequences of the patient's drinking or drug use?

E: Taken a drink in the morning as an "Eye opener" to decrease hangover or withdrawal?

A single positive response suggests that the clinical decision to prescribe opioids to the patient must be considered in relation to a potential for abuse and addiction. It does not mean that opioid use will become problematic or that opioids are contraindicated, just that you should carefully determine if the therapeutic benefits of prescribing an abusable drug is in the patient's best interest. If you deem a controlled substance is appropriate, you must exercise particular care in crafting your patient-physician agreement (whether verbal or written) and your risk management plan for monitoring and follow-up.

Many other tools exist to help screen for addiction or abuse and are listed in Appendix A. However, no one tool will be entirely reliable and the astute clinician will recognize that the signs of abuse or addiction may not be readily or immediately apparent in the typical clinical setting. If suspicion is raised for a given patient, information about previous problems with substance abuse may be obtained from a collateral source, such as a family member, friend, or other health care professional. Treatment is not required to commence until the physician is comfortable with the integrity of the situation. Understanding the signs and

symptoms of abuse or addiction will help guide questions. Feeling rushed to make a prescribing decision may in itself reflect a clinical problem (not related to the issue of abuse or addiction) that is worthy of review and discussion with the patient.

Necessity of a Comprehensive Physical Examination

Although Medicare and other institutions have defined what constitutes a physical examination for purposes of coding and reimbursement, exactly what comprises an appropriate or acceptable physical examination for pain is not well-defined, largely because it will differ from case to case. Regulators who expect to see a physical examination as part of the evaluation that leads to appropriate pain care involving controlled substances assume that a basic, if not focused, examination is warranted. The exact components of the examination are left to the judgment of the clinician who is expected to have performed an examination proportionate to the diagnosis that justifies a treatment.

For instance, it might be expected that a patient treated with opioids for chronic low back pain will have at least received a basic examination of the lumbar spine. Such an examination might reveal pathology that could be amenable to other treatments, perhaps some with less risk. Even if the physical exam does not offer clues in the case of some pain disorders, this cannot be confirmed until an examination is completed. Unless due diligence is evident with a documented physical examination, a physician's decision to begin a treatment that carries risk may be questioned.

Exceptions

It's not always possible to obtain a thorough history or evaluation for a patient. In the emergency department, the operating room, at night or on weekends, a physician or surgeon may not always be able to verify the patient's history and past medical treatment. In such circumstances, physicians must balance the need for vigilance about potential addiction or diversion with the need to treat the patient's pain. As with most treatment decisions, an approach based on risk versus benefit must determine the appropriate response. Physicians are commonly faced with risks associated with treating as well as with withholding treatment. Too often, it is impossible to know which risks are more likely and the clinician must choose to either avoid suffering and treat, accepting the potential risk for abuse or choose to prevent potential abuse and not treat, accepting the risk that the patient might suffer unnecessarily. Such decisions must be based on the long-term impact of the treatment, its duration, and the potential for diagnosing an adverse outcome were it to occur. For example, it would be acceptable practice in the case of a complaint of pain in the ER to prescribe small amounts of an opioid analgesic that would get the patient through to the following day until a clinician with a longitudinal relationship with the patient is available to follow up. The potential harm from undertreated pain, weighed against the limited potential harm of a few opioid pills, may support this determination.

Assessing Risk and Benefit

Physicians must routinely balance the potential risks and benefits of any treatment plan. But in the face of the complexity of pain, as well as the specter of scrutiny from healthcare regulators and law enforcement, it's easy to become paralyzed and decide that the least risky course is to not treat the pain aggressively or at all. But doing nothing can be the riskiest decision of all. For example, consider the case of a 76-year-old woman who comes into an emergency room with rib fractures. Adequately treating her pain is not just a matter of relieving her immediate physical problem: inadequate lung inflation and efforts to suppress coughing because of pain increase her risk of pneumonia and death. While most cases aren't this clear or dramatic, ongoing pain erodes quality of life and slowly deconditions a person's physical, emotional, and spiritual well-being. Both directly (via inappropriate activation of stress-related hormones) and indirectly (by inducing inactivity, insomnia, anxiety, or depression), pain compromises the body's defenses and leaves sufferers vulnerable. Uncontrolled chronic pain also undermines the management of any pre-existing chronic condition, such as diabetes, cardiovascular disease, and psychiatric conditions such as anxiety or depressive disorders. Chronic pain in combination with depression increases the risk of suicide.

Looking at the complete landscape of pain and its collateral damage, it is clear that the decision whether or not to treat pain offers physicians no risk-free option. If the risk to the patient associated with a given treatment outweighs the risk of withholding that treatment, then other less risky treatments must be considered. Although physicians should not feel compelled to use any treatment modality (including opioid analgesics), the risk of non-treatment must always be factored into any pain management

decision; not treating pain is often not a "safe" option. This may seem obvious, but physicians face patients in pain each day and choose what they perceive as the lesser of evils: less treatment as a means to avoid "risk."

Another risk posed by nontreatment or undertreatment of pain affects the physician, but not the patient directly. Physicians have been successfully sued for not treating pain aggressively. For example, the 2001 *Bergman vs. Eden Medical Center* case involved a physician who was found guilty of "elder abuse" arising from alleged under-prescribing of pain medication. This jury brought a $1.5 million verdict against this physician, and the jury was a single vote away from levying fines for much higher damages. This case led the California legislature to pass a law requiring the Medical Board to publicly declare its policies on how it investigates physicians in pain cases and requiring all California physicians to have mandatory continuing medical education on pain and end-of-life care. A more recent California case, in which a physician was accused of elder abuse for under-treating pain, was settled just prior to the start of the trial for an undisclosed sum. In this case, the Medical Board formally and publicly sanctioned the physician for undertreatment of pain. Even though such cases represent rather extreme situations, these legal precedents sound a warning that there are risks associated with undertreating.

This does not imply, however, that all patients must be treated aggressively with opioids or any specific treatment. It simply means that all patients complaining of pain deserve adequate assessment and treatment based on consideration of risks and benefits to the patient. When transparent documentation provides the rationale for treatment decisions, physicians should feel comfortable that they have done their best to provide appropriate patient care while meeting their fiduciary obligations as "officers of the public health."

Summary

This chapter has reviewed the key elements of effective patient evaluation. Despite modern diagnostic and evaluative tools, pain remains an untestable hypothesis. Nonetheless, the evaluation and history taking of patients in pain can be improved by: taking control of your time; focusing on the patient, not the pain; and using reflective listening skills. Be alert to any signs that a patient may be minimizing his or her pain. And when considering use of a controlled substance in pain treatment, take a substance abuse history, and as in any therapeutic intervention, pay close attention to the risk management plan. In doing so, the risks involved in not treating must always be factored into any pain management decision; not treating pain is often not a "safe" option.

References

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Chapter 2: Creating a Treatment Plan

"The written treatment plan should state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the physician should adjust drug therapy to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment."
—*FSMB Model Policy*

Because measuring pain is fundamentally an untestable hypothesis, the use of subjective reports of pain relief as the sole outcome of treatment will be difficult to measure objectively. Indeed, the very notion and practice of "pain relief" often contains a hidden assumption: that it's possible and desirable to "relieve" pain completely. Everyone lives at certain times with varying degrees of physical and/or emotional pain or discomfort. People also differ significantly in their pain tolerance and have individual thresholds at which pain impairs function. The rare cases of people with a congenital inability to feel pain demonstrates (usually tragically) the profound disadvantages of a life with "zero pain."

Ironically, the traditional 0 to 10 pain scale used so often in clinical care perpetuates this misconception: that the ideal or attainable condition is "zero pain." It's a small step from this subtle assumption for doctors (and their patients) to assume that the goal of pain treatment is the *elimination* of pain. This chapter will review some of the pitfalls of this approach. Even the primary goal of pain *reduction* may miss an essential point: the direct sensation associated with pain is not the only important variable associated with a patients complaint of pain and may not be the most important feature of the overall presentation. A critically important part of understanding pain, as a means of formulating an effective treatment plan, is to look beyond the pain sensations themselves to how those sensations are affecting and possibly eroding a patient's quality of life. Specifically, how is pain affecting the patient's functioning in daily life?

From Analgesia to Functioning: A Necessary Paradigm Shift

Since pain impacts all domains of a patients' life, complete evaluation of pain involves looking into the *effects* that these noxious signals are having on physical and psychosocial functioning. This knowledge is critically important for creating the solid treatment decisions and management plan envisioned in the *Model Policy*. Shifting from analgesia alone (or uni-dimensional pain intensity scores) to a function-based paradigm offers the following tangible advantages:

- Treatment goals become more objective and verifiable (not relying on subjective reports alone);
- Individual differences among patients, both in terms of pain tolerance and functional goals, are respected;

- An individualized evidence base is created for making appropriate risk/benefit decisions on pain treatment options; and
- Prescribing decisions (including decisions to wean a patient from a drug regimen) are tied to multidimensional outcomes, many of which may be objectively demonstrable to the clinicians and the patient.

Most important, a function-based treatment strategy offers the promise of increasing your patients' quality of life and subsequently decreasing the burden of their pain. Under normal circumstances, pain is an alarm that warns us of impending or actual harm. It is designed to grab our attention, and when pain is severe enough, to make it impossible to attend to anything else. Thus, when the alarm itself is injured or malfunctioning, pain does not turn off normally and the constant drain on attention undermines the affected individual's ability to attend to the other aspects of his or her life—often aspects that make life worth living. Chronic pain intrinsically diminishes one's capacity to function and subsequently erodes the basic elements of daily life, such as physical activity, concentration, emotional stability, interpersonal relationships, and sleep. This can, in turn, degrade role function, such as at work or home, leading to depression, anxiety, and insomnia, among other comorbidities. While significant pain worsens function, relieving pain should reverse that effect and improve function. Simply "feeling better," without improving functioning in some aspect of an individual's life, may reflect an inadequate outcome. The most successful chronic pain management includes regaining collateral losses associated with that pain.

This is a paradigm shift for many physicians, most of whom have been trained to focus almost exclusively on pain sensation and intensity—believing that the sole outcome is to reduce or eliminate a patient's intensity rating. But reducing a patient's pain score from, say, 9 to 3 is only one piece of a much larger puzzle. Particularly when treating chronic conditions for indefinite periods, it is not enough that patients say they "feel better." Depending only on such a purely subjective outcome can easily lead a physician to overlook evidence that a medication is ineffective or is producing side effects that may be reducing the patient's quality of life. In some cases, pain relief may occur without significant functional gains but on more thorough assessment, function may be found to have deteriorated. The possible reasons for this are many, including side effects, use of analgesic medications for secondary purposes such as sleep or anxiety rather than pain, or even frank abuse or addiction. Even if a medication is effective for a certain symptom, its side effects may present risks that outweigh benefits. A broad perspective and a comprehensive history are required in order to assimilate the salient facts that inform more carefully reasoned treatment decisions. Reliance solely on patient self-reporting also, of course, makes it easier for patients to deceive clinicians and themselves about their treatment outcomes, including when problems relate to drug abuse.

Setting Functional Goals

Evaluating treatment effectiveness by linking pain relief to functional gain makes many physicians uneasy. It is understandably difficult to subjugate a patient's positive subjective report of improvements in pain intensity to objective evi-

dence that functional gains have or have not been achieved—or, worse, that actual harm is taking place. But analogous situations are frequently encountered in other realms of medicine. For example, if a diabetic also has problems with chronic vasculitis, corticosteroids may effectively ease some of his or her symptoms. But corticosteroids, amongst other risks, worsen glucose control with serious consequences in a diabetic. Diabetic patients who would argue that they should be chronically maintained on corticosteroids because it is the only way they feel well challenges the physician who must make a rational clinical decision in the context of the severe toxicity of chronic corticosteroids in diabetes. No reputable physician would normally accommodate such a request except under highly select circumstances (e.g., end-of-life care where comfort is the principle goal of treatment). Most would clearly recognize that the risks outweigh the benefits. The physician is forced to say, "I'm sorry, but I can't give you this medication even though it makes you feel better because it's going to harm you in the long run." A patient who continues using an opioid medication, but whose quality of life is either unchanged or actually worsens, may well be in the same boat—and our response as physicians must be the same: "This treatment is not working well because . . . We can do better so let's find a more effective way to both control your pain and improve the quality of your day-to-day life (or help you become more functional)."

As illustrated by the case example below, some patients may report large changes in their pain score even as their quality of life erodes.

Contrast this case with the patient who reports that her pain dropped from 8 to 6 but is no longer bed bound, is

Case Study

Mike was a 38-year-old construction worker with lumbar disc injury. After laminectomy and fusion surgery, the expected bone regrowth didn't occur and the fusion surgery was repeated. This fusion appeared to work, but his pain continued. Several nerve block procedures failed to bring relief.

After several housebound months, Mike sought help at a nearby pain center. He lacked energy, slept through each night in his reclining lounge chair, and was often irritable and short-tempered with his wife and children. He complained that the hydrocodone he was prescribed wasn't working anymore. His wife reported that Mike had used various drugs in the past and currently used both alcohol and cannabis.

His physician negotiated a realistic function-based treatment plan for Mike. His initial goals were to sleep in his bed again, attend a function at his son's elementary school, enroll in a pain education class, and begin a program of gentle but long term physical therapy. Four weeks later Mike had titrated up his opioid dose as prescribed. "The medication is really working doc," Mike said. "My pain's gone from an 8 to a 2 most of the time."

But under questioning it became clear that Mike had not actually made progress. He was still sleeping in the lounge chair. He missed the school science fair. He had only seen the physical therapist once. He also wasn't sleeping well . . . even though he felt sleepy most of the time.

The physician realized that the sedation he was experiencing was interfering with his progress toward functional goals.

After considerable patient education and negotiation, Mike agreed to taper off the opioid and try a new regimen of a non-amphetamine stimulant in the morning and a sedating medication for the evening. This normalized his sleep/wake cycles and left him with more energy during the day. He used non-opioid analgesics for his pain.

Four weeks later, Mike had attended five meetings of a chronic pain support group, and several sessions with a pain psychologist who taught him skills for coping, distraction, and relaxation. His wife reported that he had been regularly attending physical therapy. Twelve weeks later Mike looked relaxed and alert. His pain was not gone; he said it varied from about a 3 to a 5 (out of 10) from day to day. But he said he could live with that. He was moving around, making slow but steady progress in physical therapy, and becoming socially active. He was benefiting from a positive feedback loop: a relatively minor reduction in his pain led to improvements in function. This, in turn, further reduced the importance of pain in his life, which further increased his function.

able to bathe herself again, and is starting to engage in small amounts of exercise. Clearly this is an example where the patient with the greater reduction in pain score should be viewed as a treatment failure and the patient with the more modest pain score reduction is a treatment success. A 20-percent reduction in a pain score (i.e., two points on the standard pain scale) may not seem significant, but it is a perfectly acceptable goal when it produces significant benefits for a patient, as illustrated in the chart below.

Activities Impaired by *Increasing* Pain Severity*

				Walk	Relate Walk
			Sleep	Sleep	Sleep
		Active	Active	Active	Active
		Mood	Mood	Mood	Mood
	Work	Work	Work	Work	Work
Enjoy	Enjoy	Enjoy	Enjoy	Enjoy	Enjoy
3	4	5	6	7	8

>>>>>>>>>>>> Worst Pain Rating >>>>>>>>>>>>

* Assessed in cancer pain patients
Source: Cleeland, C.S., and K.M. Ryan, *Ann. Acad. Med. Singapore*, 1994,23:129-138.

The illustration reflects the typical 0 to 10 pain scale as it impacts function at scores ranging from 3 to 8. It clearly shows how function is progressively impaired as the pain rating increases, and conversely, how seemingly modest reductions in pain can translate into dramatic functional improvements as pain ratings are reduced. A patient told that a specific treatment will reduce his or her pain by 20

percent may be unimpressed by this goal. In some cases of chronic pain, the spiraling loss of function may be a paramount concern, and halting a pattern of progressive loss of function and other losses related to pain may become a functional goal in itself.

A single pain score may be important to patients as they may have learned through other medical experiences that it is important to their clinicians as a quantitative yardstick with which to effectively communicate with their health care providers. But pain is so subjective that a single value on a single visit may have much less utility than pain scores used to help monitor changes over time. If the treatment outcome is framed, instead, in terms of the reclaimed function through a few-point reduction on the pain scale, they may be much more likely to see this as a major positive outcome and commit to this treatment goal. Reductions in pain scores are nonetheless important and must be honored and incorporated. Subjective pain relief is valuable and desirable. However it is a potential problem when subjective pain relief is used in isolation and as a sole determinant of treatment outcomes for a chronic condition. In chronic pain management, it is often best used as part of the primary treatment outcome with the overarching goal of functional improvement.

Function and Controlled Substances

Switching to a function-based paradigm for creating treatment plans has particular value in the area of controlled substances, because function offers a useful way to differentiate a patient who is truly addicted from one who has a similar appearance but is not. This differentiation is

grounded on the fact that addiction (as well as pain) leads to dysfunction while pain relief should improve function. When given adequate pain relief, persons in chronic pain can gain or maintain function in their lives. Addiction, on the other hand, involves drug use that causes dysfunction in one or more spheres of a person's life. Addicts have a disease that impairs their ability to control or modulate their use of a drug despite the dysfunction and harm that it incurs. In the setting of active addiction, function does *not* improve with exposure to the drug. Although many cases where analgesic trials do not lead to functional improvement are caused by something other than addiction or abuse, the lack of functional improvement always indicates a problem with the treatment or some other facet of the patient's life that deserves attention. At the very least, in cases where analgesic trials do not lead to functional improvement, re-evaluation should occur, utilizing a differential diagnosis that considers substance misuse, diversion, abuse, or addiction.

A lack of function or dysfunction that is manifest in a treatment program may turn out to have its roots in function-limiting side effects, such as sedation, or may be caused by untreated affective disorders that are commonly associated with chronic pain. However, sometimes the manifestation of dysfunction will represent addiction, diversion, or abuse, a distinction that may be difficult to make without objective measures. Putting functional goals at the heart of a treatment plan, in other words, can shed valuable light on the sometimes confusing presentations of patients in pain. (The subject of addiction versus pseudoaddiction is covered in more detail in Chapter 4.)

As mentioned in the previous chapter, the phrase "universal precautions" has been borrowed from the field of infectious diseases. The term refers to a standardized approach to the assessment and ongoing management of *all* patients with pain. Just as it is impossible to predict if patients (or their body fluids) will harbor an infectious agent, it's impossible to predict with any degree of certainty which patients in pain will abuse prescription medications. Using standardized assessments and approaches for *all* patients, such as written agreements, random drug screening, or screening instruments for risk of abuse, makes it possible to offer a broader safety net that avoids potential disparities in care, helps meet requirements for informed consent, improves patient education and participation, and minimizes overall risk. If logistical or financial constraints limit the ability to pursue this broad strategy, an alternative is to apply randomized screening only on high risk patients or patients exhibiting aberrant behavior. However, since we are not adept at determining who is and is not at risk for opioid abuse, such approaches have risk for stigmatizing patients and potentially creating disparities in care.

Getting Started

You don't need expensive interventions or high-tech diagnostics to embark on a function-based treatment plan. All you need is a pen, paper, and the information you've gleaned from a basic conversation with your patient. The functional goals of a treatment plan must be achievable and realistic. Progress is usually slow and gains are made one step at a time. In the case of chronic illness marked by

longstanding deconditioning, recovery requires reconditioning that may take weeks or months. Patients should be educated about this need for reconditioning and it must be stressed that the process is a marathon, not a sprint. Experience shows that if a patient can achieve one goal, his or her motivation and attitude improve, making the next goal that much easier to achieve. As with other life pursuits, "The key to success is success."

Here, for example, is how a set of functional goals could be set up for "Mike," the construction worker featured in the case study earlier in this chapter. Although Mike was focused exclusively on his pain and need for relief, the larger goal for any physician (after sufficient medical evaluation for a treatable lesion) should be to find a strategy that would improve his activity level, restore his self-esteem, and rebuild his quality of life. Often the best place to start is with a simple yet important question: "What is it that you're going to do on this medicine (or treatment) that you can't do now?" Sometimes patients won't know how to answer at first because they are unused to thinking in terms of functional goals. They might say, "I don't know . . . I just want to feel better, that's all."

As just explained, this is an understandable response, but it does not help to develop a set of realistic functional goals and some "hard" measures by which to evaluate outcomes. For example, upon further questioning Mike might want to sleep in his bed again instead of the reclining chair, attend a function at his son's elementary school, attend a pain education class, and begin a program of gentle but long-term physical therapy. He might agree to bring records from his class and physical therapy sessions and

have his wife confirm his progress in the other areas. Both physician and patient would now have the start of a road map by which to measure progress, and the physician would have evidence on which to base treatment decisions.

This approach also lays the foundation for making decisions about changing the course of, or even terminating, treatment in cases where goals are not met, adverse effects outweigh benefits, or in rare cases where a person is knowingly deceiving a physician to procure opioids for illicit purposes. For persons who intend to abuse drugs that are being prescribed to them, participating in a program with expectations for objective functional outcomes will present a sizeable barrier. Many such individuals may seek care elsewhere rather than undertake the effort of participating in a functional outcomes charade.

Components of an Effective Treatment Plan

A function-based treatment paradigm offers both the clinician and patient many benefits that can liberate a treatment course from the often murky terrain of chronic pain management. As you integrate this approach into your practice, keep these principles in mind:

- Elimination of all pain (i.e., "zero" pain) is usually neither possible nor desirable;
- A patient's pain score is just one of many variables related to overall status and potential for recovery;
- Treatment goals should not be set *primarily* in the form of changes in pain scores;
- Seemingly insignificant pain-score reductions may actually be extremely significant in terms of reclaimed function;

- Functional goals must be set collaboratively between patient and doctor, be realistic and achievable, be meaningful to the patient, and be verifiable;
- Functional goals must be revisited and recalibrated at regular intervals by both doctor and patient; and
- Because patient values and the functions they desire in life vary, each patient will have a unique set of functional treatment endpoints.

Although using functional outcomes may add some work to the start of a treatment plan, it will pay dividends over time. As noted above, a functional plan need not be onerous, complex, or elusive. On the contrary, a commonsense and individualized approach should result from asking simple questions, respecting the patient's values, and targeting goals of importance to the patient, starting with the most attainable and progressing over time to greater challenges. Goals must be periodically followed up and outcomes assessed, using the results to determine the direction of future care. At some point, patients may plateau at a certain level of function and each clinician, in consultation with the patient, will have to use their clinical judgment to determine whether this is acceptable or changes are needed. Even after a plateau has been reached in which stable medications are offset by stable function at an acceptable level, ongoing periodic review with follow-up functional assessments are necessary to be able to detect any decline or improvements that may occur over time.

Summary

Chapter 2 explored how to create effective treatment plans for patients in pain. In formulating a plan, targeting direct

sensations associated with pain are not the only important feature to focus on. Complete evaluation and planning means looking beyond the pain signals to the effects that those signals have on physical and psychosocial functioning. Optimal outcomes include "feeling better," but are best objectified with improved functioning in some or multiple aspects of an individual's life. Switching to a function-based paradigm offers a useful way to differentiate a patient who is succeeding with an analgesic treatment from someone who is not and may even be abusing, diverting, or addicted. Attention should be paid to even small reductions in the pain score, since they may be extremely significant in terms of reclaimed function. Sustained success will require that functional goals are revisited and recalibrated at regular intervals by both doctor and patient.

Chapter 3: Informed Consent and Agreements

"The physician should discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient or with the patient's surrogate or guardian if the patient is without medical decision-making capacity. The patient should receive prescriptions from one physician and one pharmacy whenever possible. If the patient is at high risk for medication abuse or has a history of substance abuse, the physician should consider the use of a written agreement between physician and patient outlining patient responsibilities, including: urine/serum medication levels screening when requested; number and frequency of all prescription refills; and reasons for which drug therapy may be discontinued (e.g., violation of agreement)."
—*FSMB Model Policy*

Like all treatments, effectively treating pain requires a plan that will often hinge on a careful bilateral negotiation with the patient. In medicine, any treatment plan should constitute an implied agreement between a physician and a patient. Formalizing a treatment plan by putting it in writing can serve many helpful purposes, not least of which is obtaining and documenting informed consent. (The general subject of documentation will be covered more thoroughly in Chapter 6.) A written patient-physician

agreement can serve to achieve a complete and uniform process, as well as help deal with any potential curves or bumps that may occur along the road. Such an agreement, often termed a patient care contract, can cover many different facets of care ranging from risk/benefit assessment and informed consent to administrative policies or any other educational issues that the clinician believes should be emphasized. Written agreements can also improve the coordination of care among a team of healthcare providers when they all are required to sign the agreement. (The articles in the suggested reading at the end of this chapter provide more details about these approaches.)

Any written agreement should document all the major points you have covered and agreed upon with the patient. Some pain-management centers use an agreement or contract with all patients as part of their standard practice, because selective use of these tools can be perceived as potentially reflecting prejudicial bias. Some programs apply these agreements or contracts with all patients who chronically receive any opioid-containing medication, and some have even proposed generalizing the practice to include a written agreement with all analgesic treatments. A clearly-written understanding of the agreed-upon treatment regimen helps to enlist patient adherence, even in regimens that do not include opioids. Although opioid prescribing may include more risk-management and monitoring obligations than non-opioid analgesic regimens, any treatment regimen carries varying degrees of benefit versus risk. Regardless of whether or not a physician is prescribing a controlled substance, there are tangible advantages to incorporating risk education information into a clear and transparent agreement process.

It is worth noting that the term "agreement" is perceived by some to be more acceptable to patients than "contract"—though from a legal standpoint, any written or oral agreement between a doctor and a patient may be considered a "contract" and both parties should treat them as such. Be sure that the terms in any agreements you use are understood by your patients, acceptable, attainable, and consistent with your practice.

Components of an Effective Agreement

Crafting these agreements may add some up-front time to patient care but provides a number of advantages that will benefit any patient and any treatment regimen. Written agreements:

- Engage the patient in a collaborative decision-making process;
- Assist in framing expected outcomes with specific functional goals and clarify the patient's role and responsibility in attaining these goals;
- Serve as motivational reminders to the patient (and his or her caregivers) of the specific goals agreed upon with the physician;
- Serve as informed consent forms for a variety of treatment approaches. (Be sure to obtain expert advice as to what constitutes informed consent, and adequate documentation thereof, in the jurisdiction(s) in which you practice.);
- Help avoid misunderstandings or distortions of understanding over time;
- Provide a foundation for later decision-making about changes in medications if functional goals are not

achieved, or even termination of treatment if problems arise (such as aberrant behaviors that cannot be otherwise managed—see pages 61-64); and

- Potentially enhance the therapeutic relationship between patient and doctor by enabling clear communication and expectations.

Although examples of standard informed consent agreements for opioid treatment are available at professional society websites such as the American Academy of Pain Medicine (www.painmed.org), many variations of treatment agreements are possible and they can be tailored for specific types of treatment. (Some sample agreements are available through links provided at www.fsmb.org/pain.) They can offer fixed language or include "open" areas to be filled in with specific and unique aspects of the patient's treatment plan. For example, a list of functional goals can be generated within an agreement (written in by hand or typed into a computer-based form and printed out for signing). Clinicians may want to consider adding any of the following common elements to their treatment agreements:

- Education about the risks and benefits of the agreed-upon treatment;
- Clarification of goals for treatment decisions;
- Statements relating to expectations around individualized goals and agreed-upon processes for documenting progress;
- Need for the patient to inform the treating physician of relevant information (i.e., side effects, use of other medications, changes in condition);
- Statement of time frame for which the agreement is in effect;

- Requirements for including or communicating with additional healthcare providers involved (e.g., primary care physician, pharmacist, psychologist, physical therapist, etc.);
- Who receives the agreement, where the agreement is kept, etc.;
- Statement of patient privacy rights;
- Administrative policies and expectations (e.g., missed appointment, follow-up, appearing without appointment, single pharmacy requirements, expectations of how emergencies will be handled, etc.); and
- Specific terms for administrative or other termination (e.g., abusing medication, missed appointments, violating agreement, inappropriate behavior, no improvement, pregnancy, tolerance, toxicity, etc.).

Treatments involving controlled substances may be well served by including the following additional elements:

- Patient responsibilities on improper use of controlled substances (e.g., overdosing, seeking medication elsewhere, selling medication, stopping medication abruptly);
- Limits on replacing lost medication or changing prescriptions;
- Limits on drug refills (e.g., phone allowances, mailing or faxing policy, normal office hours, etc.);
- Agreement to comply with random drug screens;
- Education on side effects (including tolerance and withdrawal);
- Education on addiction risks and behaviors;
- Pharmacy issues (e.g., one pharmacy, in-state pharmacy);

- Additional risks (e.g., interactions with other drugs, masking conditions, driving safety, misusing, pregnancy);
- Legal considerations (if applicable because of state laws);
- Need for single prescriber for all opioid prescriptions; and
- Terms regarding specific medication (e.g., type prescribed: long-acting, generic brands, etc.).

Effective Communication

In addition to including all relevant aspects of a proposed treatment in a written agreement, physicians should discuss the risks and benefits of the use of any controlled substances with the patient (or with the patient's surrogate or guardian if the patient is without medical decision-making capacity). Patients must be given the opportunity to ask questions, and physicians should "check in" with patients to ensure they understand what they are being told. A treatment that is simply handed to a patient without his or her input, or which is hastily explained with the potential to be misunderstood by a patient, will not suffice. Reviewing the consent form and not treating it as a mere formality to be buried in the chart transforms this from a perfunctory document with the sole purpose of protecting the physician's practice to a living cornerstone of understanding about the agreed upon course of care that may assist in treatment success.

Since any beneficial treatment always carries some risk, and more aggressive treatments usually carry greater risk, sharing these concerns and decisions about risk is critically important. The patients, after all, will ultimately take on the work of treatment adherence, tolerating possible side

effects and the challenges of achieving functional improvement. Moreover, they will bear the consequences of any adverse outcomes. A paternalistic approach, where the physician is the sole decision-maker, may result in half-hearted patient acceptance without investment or full commitment to the treatment. If expected outcomes are not achieved, the head of this treatment regimen—the physician—will then be responsible. Although it may be considered noble for the clinician to shoulder the responsibility, it is usually not in the best interest of the patient. The incentive for success must be with a patient who clearly understands that treatment success or failure necessitates his or her participation and investment. Although the physician has ultimate responsibility for the treatment plan, he or she may be well served to take the position of the expert advisor and consultant. The patient is best served by being put in the role of chief executive officer of his or her treatment regimen.

Effective communication and patient education are integral parts of "best practices" from both an ethical and legal standpoint. A patient who does not fully understand the potential risks and benefits of a procedure or treatment cannot be said to be truly "informed" as required by both law and the ethical guidelines for medical practice. Inadequate communication on the part of a physician and the failure to educate the patient about the treatment regimen, in other words, can have serious consequences.

Summary

Key elements of informed consent and agreements were reviewed in this chapter.

In medicine, almost any treatment plan constitutes an implied agreement between a physician and a patient. Regardless of whether or not you are prescribing a controlled substance, there are tangible advantages to incorporating risk education information into a clear and transparent written agreement. Be sure that the terms in any agreements you use are completely acceptable, attainable, and consistent with your practice. A patient who does not fully understand the potential risks and benefits of a procedure or treatment cannot be said to be truly "informed" as required by both law and the ethical guidelines of medical practice. You can create treatment agreements that help meet informed consent requirements using templates that are available online or by tailoring one from the specifics of your practice.

Suggested Readings

1. Fishman, S.M., T. Bandman, A. Edwards, and D. Borsook. The Opioid Contract in the Management of Patients on Chronic Opioid Therapies. *J. Pain and Symptom Management*, 1999, 18(1):27-37.

2. Fishman, S.M., G. Mahajan, S.W. Jung, and B. Wilsey. Bridging the Pain Clinic and the Primary Care Physician through the Opioid Contract. *J. Pain and Symptom Management*, 2002, 24(3):254-262.

Chapter 4: Periodic Review

"The physician should periodically review the course of pain treatment and any new information about the etiology of the pain or the patient's state of health. Continuation or modification of controlled substances for pain management therapy depends on the physician's evaluation of progress toward treatment objectives. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. Objective evidence of improved or diminished function should be monitored and information from family members or other caregivers should be considered in determining the patient's response to treatment. If the patient's progress is unsatisfactory, the physician should assess the appropriateness of continued use of the current treatment plan and consider the use of other therapeutic modalities."
—*FSMB Model Policy*

Periodic review refers to follow-up after initiating a treatment plan. The tests performed, questions asked, and evaluations made are tailored to the patient and guided by the physician's clinical judgment. For example, a physical examination may or may not be required at each follow-up visit. (Check with your medical licensing board—some states may require a physical examination at each visit).

When controlled substances are involved, physicians must attend to predetermined treatment outcomes and be alert to a wide range of potential adverse effects. These include the common physical adverse effects of opioids such as sedation, constipation, urinary hesitancy, dry mouth, nausea/vomiting, itching, sweating, and hypogonadism, as well as more subtle behavioral effects such as mood changes, signs of drug craving or seeking, or impaired function in spheres of daily living.

Monitoring a patient's progress toward a set of functional goals (as opposed to simply asking if he or she "feels better") requires a means of measuring the progress (or lack thereof). This neither means that physicians have to become private investigators, nor that significantly more work is required as long as the goals and means of verification are clearly set up from the beginning. The key is to work with patients to create a set of realistic treatment goals and a means of charting progress towards these goals. The major responsibility of attaining those goals and presenting the evidence lies with the *patient.*

As discussed in previous chapters, patients in chronic pain suffer collateral losses that are manifested through lost function and decreased quality of life. Reviewing a patient's functional losses and desired gains is an essential part of determining an initial treatment plan and is critical to establishing useful measures for progress on return visits. Functional goals should not be extravagant or difficult to detect, but they should span as many domains of a person's life as possible: personal and social relationships, work, physical activities, hobbies, and spiritual activities. On the next page are examples of some simple functional

Functional Goal	Evidence
Begin physical therapy	Letter from physical therapist
Sleeping in bed as opposed to lounge chair	Report by family member or friend (either in-person or in writing)
Participation in pain support group	Letter from group leader
Increased activities of daily living	Report by family member or friend
Walk around the block	Pedometer recordings or written log of activity
Increased social activities	Report by family member or friend
Resumed sexual relations	Report by partner
Returned to work	Pay stubs from employer or letter confirming the patient is off of disability leave
Daily exercise	Gym attendance records or report from family member or friend

goals and ways they might be verified during periodic review.

When validation requires a report from a spouse, partner, family member, or friend, it may be useful, if the patient is willing, to have that person accompany the patient to follow-up visits. Of course, no validation scheme is 100-percent foolproof—if somebody really wants to fool a physician, he or she will find a way. But experience suggests that dysfunctional or even deceptive patients reveal themselves at some point—and repeated

requests for the kind of evidence just mentioned forces this unmasking earlier in the course of treatment. Such patients rarely are able to keep up a charade of documenting functional improvement, particularly if their general level of function is decreasing. If patients are looking for easy access to an abusable prescription drug, they may well simply go elsewhere when they see a function-based approach or when asked for evidence of progress.

But the purpose of validating treatment goals is not simply to detect abuse of prescription drugs—though it can certainly help. The real purpose of putting "teeth" into a functional goal agreement is to motivate patients to achieve their goals and to provide the physician with the information needed to determine if a given course of treatment is working or not.

The evidence you request will vary with the patient, and your clinical judgment will dictate what evidence will be necessary, for how long, and to what degree it will be needed. Remember that the patient is largely responsible for his or her therapeutic outcomes, and part of this responsibility is to provide you with evidence of his or her progress. Meeting this part of the "deal" is a functional outcome in and of itself. If a patient is unable to document or achieve the progress outlined in an agreement, this suggests a need to reassess and possibly make adjustments.

Reviewing Functional Goals

Although functional goal-setting is critically important at the outset of a treatment plan, it isn't a one-time event. Goal-setting is a process that evolves across the span of a long-term therapeutic treatment course. As is the case in

the treatment of so many other medical conditions, periodic review may mean that you and your patient collaboratively agree to continually move the functional goalposts. In these circumstances, the physician is akin to a sports coach. If a patient has achieved a goal or set of goals, you should recalibrate the goals to motivate the patient to reach the next level. For instance, if a patient, after three months of incremental improvement, has been able to return to swimming laps once a week, you might set a new goal of swimming three times a week. Conversely, if you've set an initial goal that is too ambitious, and the patient is becoming discouraged by the lack of progress, you can revise the goal downward or change it all together.

A common dilemma for physicians is a patient who resists engaging in physical activity toward functional goals because they report that any activity hurts too much. In such cases, rather than feeling forced to increase the dose of an opioid medication, physicians may wish to take a step back and re-evaluate the functional goals. All patients—even those with end-stage disease—can do some kind of physical motion at least some time during the day. It may appear to be so minimal that it doesn't "count" as an "activity," but it may nonetheless be a starting point for a functional goal—it all depends on how you define function. Patients with a chronic pain condition may initially need an exceedingly gentle but persistent exercise plan. This plan may need to specifically isolate and avoid using the most painful areas until some degree of physical conditioning has been established. Patients in chronic pain are not in a sprint—they are running a marathon that requires careful pacing and controlled, graduating exertion over sustained periods of time.

The patient who says that he or she can't exercise because of pain may simply be signaling that their exercise is starting at too intense a level or they are fearful of injury, increased pain, or even losing their identity as being "disabled." These myriad psychological barriers to initiating an upward cycle of improvement are beyond the therapeutic reach of prescription drugs or nerve blocks, reinforcing the importance of a team approach to integrated behavioral and rehabilitative pain management.

Almost all patients, however, can find some movement that does not cause pain. Finding that movement may not be easy, but it usually is possible. Doing that exercise for a while, and doing it repeatedly, can begin the conditioning process and allow for gradual increases in activity over time. Trying to do too much too soon will lead to failure, but this should never be an excuse for doing nothing.

Monitoring Adherence

Monitoring adherence to medication regimens is an imperfect science, but it remains an essential part of the overall process of periodic review. There are, at present, multiple ways to assess adherence but no single best approach exists. The simplest way is to just ask patients if they have been taking their medications as prescribed. Other methods include diaries, written agreements, tablet counts, and laboratory testing. Effective adherence monitoring usually involves combining several of these techniques.

Traditional methods of measuring adherence to medical therapies include tablet counts, diaries, and patient interviews. Such methods have a number of advantages as well

as drawbacks. Gross tablet counts are often unreliable because tablets may be discarded or possibly, in the case of opioids, hoarded, diverted, or sold, and offer no information about the pattern of medication use. In addition, containers can be lost or intentionally withheld. Patient diaries are questionable representations of reality, particularly when reflecting use of opioids or any other potentially abusable or psychoactive drug. They also may have the undesirable effect of keeping patients "tuned in" to their pain, rather than allowing them to "get on with their lives." Patient interviews are subject to favorable recall bias on the part of the patient, as well as forgetfulness, especially when the interval between drug use and interview exceeds two weeks.

Laboratory testing remains a popular part of assessing adherence to a treatment regimen involving controlled substances. However, such tests can be compromised by variability and limitations in obtaining specimens, custody of specimens, laboratory methodologies, and interpreting laboratory data. Effective use of laboratory methodologies requires understanding many details of physiology, pharmacology, and toxicology, which are topics beyond the scope of this discussion. Laboratories vary in their testing thresholds and standards. Physicians must, therefore, understand these details before using the lab data with confidence.

Some labs, for example, only report values that are found to be above a certain preset threshold. Thus, a patient might have a measurable level of a drug, but since it does not exceed the given threshold, it is reported as a "negative" finding. This might lead the clinician to suspect that a prescribed drug, which should be present at the time of drug screening,

is absent because of diversion when, in fact, the drug is possibly being taken properly by the patient. A problem on the other end of the spectrum is when a patient wants to demonstrate compliance with a given medication by taking it only prior to a scheduled screen—a practice known as "white coat compliance."

The presence and level of drugs can be detected in serum, urine, hair, and saliva. For routine drug surveillance, urine screening is most commonly used even though such screens are seldom quantitative (i.e., they usually simply confirm the presence or absence of a drug). Serum determination offers quantitative data but may not be necessary in most clinical situations. Use of serum levels of opioid analgesics in clinical practice is rarely justified, based on the wide interpatient variation in minimum effective analgesic concentration, the possible development of tolerance to analgesic or other opioid effects, and the considerable intrapatient variability in relating pharmacokinetic data to pharmacodynamic effects. Many comprehensive laboratories are expanding their urine toxicology services and limiting serum analysis to special needs.

Urine is the standard and often exclusive specimen used in laboratory screening for routine drug surveillance of opioids or other controlled substances. Advantages of urine testing include relative ease of sample acquisition, availability of rapid, inexpensive, simple testing methods, and longer duration of a positive result compared to serum. Unfortunately, urine screening is not perfect. Testing of opioids in urine is generally of two types: a screening method and a confirmatory test. Specimens found to be negative by the screening method usually

require no further analysis. It is imperative to know the sensitivity and specificity of screening tests for controlled substances, as many point-of-care screens for "opiates" do not reliably detect any opioid other than codeine and morphine, or may not report if levels are below a certain threshold. Therefore, they may give false-negative results for semi-synthetic and synthetic opioid analgesics. Positive samples may be further studied by a confirmatory test.

Confirmatory studies are necessary when the consequences of a false-positive result are significant, or when identification of specific opioid agents is required, such as morphine and codeine, rather than a class-specific opiate-positive finding. In such cases, it is advisable to use a laboratory that complies with the Substance Abuse and Mental Health Services Administration (SAMHSA) standards and to use accepted chain of custody procedures for obtaining and handling specimens. (The SAMHSA standards are available at: www.workplace.samhsa.gov/)

Managing Non-Adherent Patients

Suspicion that a patient is non-adherent should prompt a thorough investigation of underlying causes, *not* a summary rush to judgment. We all must acknowledge that in managing challenging cases and difficult patient-physician relationships, the problem is not always just with the patient. The way we interact with these patients will impact the relationship and influence treatment outcome. The difficult patient may raise a host of reactions in the clinician and recognizing these reactions is critically important to delivering the best possible care.

Be aware of the distinction between *pseudoaddiction* and addiction. Patients who are receiving an inadequate dose of opioid medication often "seek" more pain medications to obtain pain relief. This is called pseudoaddiction because healthcare practitioners can mistake it for the drug-seeking behavior of addiction. (Recall that addiction is when a person loses control over the use of a substance, uses it compulsively, and continues to use it despite harm and dysfunction.) Some common signs of pseudoaddiction resulting from inadequate analgesia are:

- Requesting analgesics by name,
- Demanding or manipulative behavior,
- Clock watching,
- Taking opioid drugs for an extended period,
- Obtaining opioid drugs from more than one physician, and
- Hoarding opioids.

Note that these same behavioral signs can indicate addiction. One way to discriminate between the two is to observe as closely as possible the functional consequences of opioid use. Whereas pseudoaddiction resolves when the patient obtains adequate analgesia, addictive behavior does not. Consultation with an addiction medicine specialist or psychiatrist may be necessary at the point when addiction becomes a concern. As always, high vigilance and tempered judgment are required with certain signs that may or may not indicate an abuse problem. (See the chart on the next page.)

It may be tempting to assume that patients with chronic pain and a history of recreational drug use who are not adherent to a treatment regimen are abusing medications. But other causes of non-adherence, such as those discussed above, should be considered before a judgment is

(Behaviors LESS indicative of addiction)	(Behaviors MORE indicative of addiction)
Express anxiety or desperation over recurrent symptoms	Bought pain medications from a street dealer
Hoard medications	Stole money to obtain drugs
Taken someone else's pain medications	Tried to get opioids from more than one source
Aggressively complained to doctor for more drugs	Performed sex for drugs
Requested a specific drug or medication	Seen two doctors at once without them knowing
Used more opioids than recommended	Performed sex for money to buy drugs
Drink more alcohol when in pain	Stole drugs from others
Express worry over changing to a new drug even if it offers potentially fewer side effects	Prostituted others for money to obtain drugs
Expressed concern to physician or family members that pain might lead to use of street drugs	Prostituted others for drugs
Asked for second opinion about pain medications	Prescription forgery
Smoke cigarettes to relieve pain	Sold prescription drugs
Ever used opioids to treat other symptoms	

Source: Passik, S.D., K.L. Kirsh, K.B. Donaghy, and R. Portenoy. Pain and Aberrant Drug-Related Behaviors in Medically Ill Patients With and Without Histories of Substance Abuse. *Clinical J. Pain*, 2006, 22(issue):173-181. (see p. 65, no. 1)

made. If for any reason a physician's suspicions are aroused, he or she has a duty and obligation to increase his or her vigilance through closer observation, increased testing, and greater involvement of consultants or other supportive clinicians. This approach is no different than for the management of any patient in whom you suspect toxicity from a drug therapy. Use of the type of patient–physician agreement detailed previously can guide such a process and may make implementation less confrontational or controversial.

Components of Effective Follow-Up

Progress toward treatment goals is seldom smooth. Reversals and patient frustration are common. Your goal is to help patients see the long view, support their efforts, and troubleshoot problems. Here are some tips for effective periodic review:

- Careful and compassionate listening;
- Attention to the entire patients, not just to their pain;
- Referral to related health professionals as needed to support a treatment plan (e.g., other medical specialists, mental health professionals, physical therapists, social workers, support group, etc.);
- Adjustments to pain medications if indicated and reasonable in the larger context of the patient's situation—linking continuation of these medications to evidence of reasonably improved function or stabilization at an acceptable level;
- Modifications, if needed, of functional goals. Goals can be scaled back if progress is lacking, or can be made more aggressive if progress is rapid;

- Revising the patient-physician agreement as needed to reflect changes in treatment regimen, functional goals, or other aspects of the patient's condition; and
- Complete documentation that offers transparent descriptions of the risks involved in the ongoing treatment plan, the risks of not taking such actions, and the ongoing risk management strategy.

Summary

This chapter examined the need for periodic review of treatment outcomes for patients in pain, particularly when controlled substances are involved. Physicians must closely attend to expected treatment outcomes and be alert to a wide range of potential adverse effects. Monitoring a patient's progress toward a set of functional goals requires a means of measuring the progress (or lack thereof). But the responsibility of attaining those goals and presenting the "hard data" may be best held with the patient. The purpose of validating treatment goals is not simply to detect abuse of prescription drugs, it is to motivate patients and help you determine if treatment is working or is problematic for any variety of reasons. Sometimes functional goalposts must be moved in order to maintain a patient's motivation. In the course of periodic review, suspicion that a patient is non-adherent should prompt a thorough investigation of underlying causes, not a summary rush to judgment. It is easy to mistake pseudoaddiction for the real thing. One way to discriminate between pseudoaddiction and addiction is that pseudoaddiction resolves when the patient obtains adequate analgesia; addictive behavior does not.